

Remarks/Arguments:

Claims 1-15, 25-27, and 35-52 are pending in this application.

Claims 1-9, 11, 15, 25-27, 36-38, and 42-52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,522,881 to Lentz (Lentz) in view of U.S. Patent No. 5,964,744 to Balbierz et al (Balbierz). Claims 10, 14, and 41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lentz as modified by Balbierz further in view of U.S. Patent No. 5,769,884 to Solovay (Solovay). Claims 12, 13, 35, 39, and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lentz as modified by Balbierz, further in view of U.S. Patent No. 5,824,036 to Lauterjung (Lauterjung).

The applicant notes that the Examiner has responded to the applicant's previous arguments. For the reasons discussed below, the applicant submits that the pending claims are patentable over the cited references.

The claimed invention is directed to an implant having improved fixation to a body lumen. Specifically, the invention provides a prosthetic component defined by a graft and a hem formed on the graft wherein the hem defines an interior space. The invention provides a cord disposed in the interior space and adapted for expanding upon absorbing fluid. As recited by claim 1, this serves to aid in fixating the prosthetic component against the body lumen. The application contains independent device claims 1, 35-38, and 41 directed to this invention. Independent method claims 25 and 42 generally recite introducing a device of the invention into a body lumen and then contacting the cord with fluid, while independent method claim 43 recites introducing a device of the invention into a body lumen and then removing an impediment to fluid flow to allow the fluid to contact the cord.

In support of the rejection of independent claim 1, the Examiner relies on *In re Hutchinson*, 69 USPQ 138 (CCPA 1946) for the proposition that "the recitation that an element is 'adapted to' perform a function is not a positive limitation but only requires the ability to perform." The Examiner goes on to state that an element that is adapted to perform a certain function does not constitute a limitation in a patentable sense. Consequently, the Examiner concludes, "In this case since the reference structurally meets the claim it is fully capable of performing the function." The applicant contends that the basis for reaching this conclusion is incorrect. First, *Hutchinson* does not support the basis cited in the Office Action. Moreover,

more recent case law such as *In re Venezia*, 189 USPQ 149 (CCPA 1976) holds that "adapted to" language does, in fact, impart a structural limitation to a claim. Finally, the more recent case is endorsed by the MPEP, which provides guidance that such claim language should be deemed to present structural attributes of a claimed invention. MPEP § 2173.05(g).

Turning first to *Hutchinson*, the Court of Customs and Patent Appeals in that case affirmed the decision of the Board of Appeals affirming the Examiner's rejection of certain product claims. Claim 42 was deemed representative and recited in its preamble, "As an article of manufacture, adapted for use in the fabrication in the use of a metal template or the like suitable for metal-working operations, a laminated unit comprising a backing element" The claim went on to recite other limitations within the body of the claim such as an adhesive and a surface paper bonded to the backing element by the adhesive. In attempting to overturn the Board's holding, the appellant had emphasized various parts of the claim, including the preamble quoted above which contained the "adapted for" language. The Court dealt with this language in only one paragraph of the case, where the Court stated:

The first phraseology italicized by appellant is the introductory clause to the effect that the laminated article is "*adapted*" for use in making a template or the like. This does not constitute a limitation in any patentable sense.
Id. at 141.

As can be readily appreciated it, there can be numerous reasons why the above-quoted preamble of claim 42 could be deemed not to be a limitation in any patentable sense. First, the text is a preamble limitation (or "introductory clause" as characterized by the Court) and it could be for that reason alone that the Court did not give any patentable weight to this phrase. Second, this phrase is also a mere "use" limitation and could have been discounted by the Court on that basis. In addition, the use of "in making a template *or the like*" contemplates a broad range of uses and does not provide any definite limitation to the claimed article. To conclude that the Court necessarily reached its holding that the phrase does not constitute a limitation in a patentable sense solely because of the term "adapted" is tenuous at best. Along these lines, it should be noted that the Court earlier mentioned that it italicized particular parts of the claim in a manner consistent with the italicization scheme used by appellant. *Id.* at 140. In any event, the Court did not distinguish between function and structure in this case, nor did it have to as the above-quoted discussion about the "adapted to" language is mere dicta. In particular,

the Court went on to say that, even if the phrase did constitute a limitation, it is anticipated by a prior art reference. *Id.* at 141.

As mentioned above, a case closer on point and decided thirty years after *Hutchinson* is *In re Venezia*. In *Venezia*, the claim at issue was directed to a splice connector kit comprising a pair of sleeves of elastomeric material, electrical contact means adapted to be affixed to a terminus of an exposed conductor, and a pair of retaining members adapted to be positioned between the sleeves. The Board of Appeals had agreed with the Examiner that the claim did not comply with 35 U.S.C. §§ 101 and 112, second paragraph. In so holding, the Board cited *In re Collier*, 158 USPQ 266 (CCPA 1968) as follows:

We agree with the Board, however, that the claim does not positively recite structural relationships of the two elements.

The Court of Customs and Patent Appeals in *Venezia*, however, distinguished the facts of *Venezia* from *Collier* and held that "the claims [in *Venezia*] do define the metes and bounds of the claimed invention with a reasonable degree of precision and particularity." In particular, after quoting the elements reciting the "adapted to" language, the Court stated, "rather than being a mere direction of activities to take place in the future, **this language imparts a structural limitation to the sleeve**" (emphasis added). As mentioned above, this case has been quoted by the MPEP to support the proposition that such language serves to precisely define present structural attributes of interrelated component parts of the claimed invention." See MPEP § 2173.05(g).

With respect to the rejection of Lentz in view of Balbierz, the applicant contends that the language "adapted for" is a positive limitation that precisely defines physical attributes of the cord (what it is), rather than what it does: "A cord disposed within said interior space adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen." As in *Venezia*, this limitation further defines structural limitations of the cord and how the cord interrelates with the prosthetic component because this language fairly conveys to a person of ordinary skill in the pertinent art that the cord, as claimed, is an expanding and fluid absorbing cord and aids in fixating the prosthetic component against the body lumen. This incorrect interpretation of the "adapted for" phrase in the Office Action mandates withdrawal of the rejection of the independent claims. Moreover, the applicant notes that the Examiner mentioned that "the reference structurally meets the claim." It is not clear which "reference" the Examiner is referring to in this case as neither Lentz nor Balbierz structurally

meet the claim in its entirety. As mentioned in the previous response and as elaborated on below, neither reference structurally meets the claim nor is either capable of performing the specified function.

To establish a *prima facie* case of obviousness, MPEP § 2143 sets forth three requirements. First, there must be some suggestion or motivation to combine the references. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all of the claim limitations. With respect to the rejection of Lentz in view of Balbierz, the applicant contends that, at the very least, there is no suggestion or motivation to combine these two references.

As stated in the previous response, Lentz is directed to an implantable prosthesis 10 having integral cuffs 20 and 22. Lentz discloses, and contemplates, inserting only a stent 28 into the cuffs and expanding the stents to anchor the conduit in the body vessel. The cuffs define a slot 20a and 22a between the cuff and body where the stent is inserted. As described in Lentz, the cuffs are used to house a stent, which is used to affix the prosthesis in place by radial expansion against the inner wall of the body lumen, in a known manner. Col. 3, lines 31-60, and col. 5, lines 18-21. In other words, the only place for the stent (an important part of a prosthetic component) to be disposed in Lentz is in cuffs 20 and 22, and the only component which is envisioned to be disposed there by Lentz is a stent. As recognized in the Office Action, Lentz fails to disclose a cord disposed within the cuffs that is capable of absorbing fluid and expanding to aid in retention of the prosthesis within the body lumen.

Balbierz is relied upon in the Office Action for its teaching of a device comprising a coated polymer material that expands upon hydration. The Office Action cites Figure 12 in support of the rejection. As shown in Figure 12 and as described throughout Balbierz, Balbierz is directed to ureteral stent for assisting drainage, for example, from the kidney through the ureter. See Col. 1, lines 26-28. The parent patent of Balbierz, U.S. Patent No. 5,599,291, describes the operation in more detail of a ureteral stent at columns 4 and 5, in connection with Figure 1 of both Balbierz and its parent. Critical to its function, the stent must form a predetermined final cross-ureteral stent outer diameter to provide enhanced fluid passage from kidney 28 to bladder 22. See the '291 patent, col. 5, lines 4-9. The stent defines a lumen 32 extending its entire length with openings at both ends and may also include drainage holes 34. Col. 5, lines 13-17. In sum, to achieve its purposes, it is critical that the device of Balbierz be configured such that it allows flow along its length. Also, the way in which the device of

Balbierz is retained in place is by the use of pigtails or enlarged ends that are blocked by virtue of a body lumen becoming narrowed, as shown in Fig. 1A.

As motivation to combine the references, the Examiner has stated that one would do so "in order to produce a prosthesis that is capable of expanding and fixating securely against the walls of a body lumen." Office Action, page 2, bottom. When viewing these two references before such a combination, and without the benefit of applicant's own disclosure, it is clear that one skilled in the art would not have been motivated to combine the references for this reason. As is clear from a review of Balbierz, it is the pigtail configuration of the ends of lumen 32 which cause the device to be retained in place. As shown in Fig. 1B of Balbierz, for example, the ends 14 and 24 have axes generally transverse to the longitudinal axis of the body lumen. It is this orientation that causes the device of Balbierz to be retained within the body lumen. The applicant is hard-pressed to see why one skilled in the art would be motivated to utilize a material of such a disclosure in a hem whose central axis is generally coincident with the body lumen, as shown in Lentz.

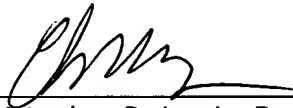
Moreover, the expansion of the device in Balbierz is to improve in fixating the device *itself*, not to improve in fixating some other component against a body lumen. On the other hand, in Lentz, the stent within the hem exerts a force on the hem and thus the prosthesis 10. This is yet another reason why one skilled in the art would not expect that the material taught by Balbierz would necessarily "produce a prosthesis that is capable of expanding and fixating securely against the walls of the body lumen" as suggested in the Office Action. Instead, when one skilled in the art would have viewed the teaching of Balbierz at the time of the invention (and without the benefit of the invention), one would have only recognized that the material of Balbierz does not exert a force on another component (e.g., a prosthesis or graft) but merely keeps itself retained in place, primarily by its transverse orientation.

Perhaps the most compelling reason mandating that there is no proper motivation to combine these references is that the proposed modification would render the prior art unsatisfactory for its intended purpose. See MPEP § 2143.01, fifth heading. Important to the prosthesis of Lentz is that stent 28 be sealed from the fluid flowing through the body vessel. See abstract, last sentence. More specifically, as described at column 5, lines 28-35, the stent 28 is shown clearly supported in slot 24, meaning that the stent is never in direct contact with either blood flowing through the lumen 32 or the tissue of the walls of vessel 34. Therefore, merely placing the material of Balbierz et al. into the hem of Lentz would not achieve the result

envisioned by the Examiner. In particular, because no body fluid would reach the material of Balbierz, it would not expand and then operate in the manner envisioned by the Examiner. On the contrary, body fluid would be prevented from contacting that material by inserting it into the hem of Lentz. Moreover, even if body fluid could have reached the material, configuring the device of Lentz in a position having an axis coincident with axis of the body lumen would preclude body fluid from flowing along its "length" to cross a narrowed body lumen.

The rejections of all of the remaining claims rely on the combination of Lentz and Balbierz. The applicant contends that these rejections are improper for the same reasons set forth above. For the reasons discussed above, the applicant respectfully submits that claims 1-15, 25-27, and 35-52 are in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,



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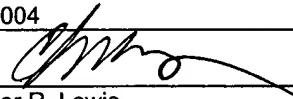
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